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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,348	01/07/2002	Gil M. Vardi	19601-000120US	2645

9629 7590 08/21/2003

MORGAN LEWIS & BOCKIUS LLP
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WASHINGTON, DC 20004

EXAMINER

SWEET, THOMAS

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/21/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,348

Applicant(s)

VARDI ET AL.

Examiner

Thomas J Sweet

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 22-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33-35 is/are allowed.
- 6) ☒ Claim(s) 1, 22-32, 36-40, 44-46 and 48-49 is/are rejected.
- 7) ☒ Claim(s) 41-43, 47 and 50-53 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 22-26, 30-32 and 36-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Penn et al. (WO 97/41803). Penn et al discloses a main tubular stent (fig. 3) having at least one side opening (54) with a plurality of laterally deployable elements (53,52) therein.

With regard to claim 24, see figure 2 which is prior to assembly as well as prior to expansion.

With regard to claim 25, upon expansion and hence after assembly laterally deployable elements (52, 53) are extended outwardly from the stent body as see in figure 4.

With regard to claim 26, see the balloons in figures 12 and 13.

With regard to claims 30 and 31, as can be seen in figure 16 the loops and struts around the perimeter of the opening of the main stent are connected there by forming a continuous band

Art Unit: 3738

that would have loops projecting inwardly towards the center of the opening when in the configuration shown in figure 2.

With regard to claim 32, as seen on figure 16, the side opening is generally circular so as to match the cross sectional flow path of the branch leg (105).

With regard to claim 36, see figure 4 with second stent 45.

With regard to claims 37-39, the claimed method reads on the method disclosed for manufacturing and deploying the stent of Penn et al (page 16). The main tubular stent of Penn et al is expanded, upon expanding of the leg portion the plurality of elements (52,53) are deflected laterally. Since, the leg portion of Penn et al is connected to the main portion, the opening (54) would be aligned with the branching body upon placement and expansion of the stent. During manufacture the plurality of elements are deflected laterally, so that the second stent can be placed in the side opening.

Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Globerman (US 5776161). Globerman discloses a method (figure 25 and the corresponding portions of the specification) including the steps of providing a stent (figures 25 and 26) having a first portion (main graft), a second portion (left graft) and a side opening (the intersection of the right graft with the main tube); expanding the first portion (no. 1 balloon); aligning the side opening with the branch lumen (by expanding balloon no.2 in the right graft); and expanding the second portion (pulling no. 1 balloon and reinflating).

Art Unit: 3738

Claims 44-46 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonald (US 5676697). McDonald discloses a radially expandable stent (fig. 2) having an expandable opening (114) with a perimeter defined by a continuous band of material (124).

With regard to claims 45 and 46, in figures 6 and 7, the side opening 114 appears to be oval (generally circular in shape) prior to expansion. In figure 8, the side opening 114 appears to be circular after expansion.

With regard to claims 48 and 49, in figures 6 and 7, the side opening 114 appears to be symmetrical about the longitudinal axis of the stent and an axis laterally across the stent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penn et al. Penn et al discloses a main tubular stent (fig. 3) as discussed above. However, Penn et al does not disclose the main tubular stent being fabricated of a material with self-expanding characteristics. It is well known in the prior art to fabricate stents of self-expanding material in the same field of endeavor for the purpose expanding the stent in place rather than using or in addition to using a balloon or mechanical expander. It would have been obvious to one of ordinary skill in the art at the time the invention was made to fabricate the stent of Penn et al out of a material with self-expanding characteristics so as to expanding the stent in place rather than

Art Unit: 3738

using or in addition to using a balloon or mechanical expander, since it is well known in the art to do so.

With regard to claims 28 and 29, Penn et al remains silent as to at least a portion of the main stent body being radiopaque. It is well known in the prior art to fabricate or mark stents with radiopaque material in the same field of endeavor for the purpose of visualization placement during implantation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the stent of Penn et al radiopaque so as to visualization placement of the stent during implantation, since it is well known in the art to do so.

Allowable Subject Matter

Claims 33 -35 are allowed.

The following is an examiner's statement of reasons for allowance: The prior art of record does not teach or render obvious a main stent body of a bifurcated stent having spine regions on the proximal and distal portions having different strut patterns.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 41-43, 47 and 50-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is (703) 308-4018.

The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

tjs



**CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**